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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,335	05/20/2008	Philippe Perovitch	0603-1002	2717

466 7590 05/11/2010  
YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
Alexandria, VA 22314

EXAMINER
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MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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05/11/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,335	<b>Applicant(s)</b> PEROVITCH ET AL.	
	<b>Examiner</b> Michael V. Meller	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/6/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of pilocarpine in the salt form, methylcellulose, sorbitol, sodium or disodium hydrogen phosphate , magnesium stearate, polyethylene glycol, hyaluronic acid, lysozyme chlorohydrate (aka lysozyme-see below explanation) in the reply filed on 4/13/2010 is acknowledged.

The traversal is on the ground(s) that the JP 07330602 reference cited previously does not apply to the instant claims under the PCT rules. This is not found persuasive because as noted on the record, the claims are properly rejected under the cited art. Thus, a lack of unity does indeed exist. The art does teach the salt form of pilocarpine and a bioadhesive polymer such as the elected methylcellulose. The claims are being examined for the above specifically elected composition.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1655

3. Claims 11, 12 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term, "lysozyme chlorohydrate" is not readily known in the art. In fact, it is known by "lysozyme". Thus, the term is confusing and should be changed to lysozyme since both terms are one and the same. One of ordinary skill in the art would readily know what the meaning of lysozyme is not lysozyme chlorohydrate. Note that in the enclosed "Resolution Oeno", the terms are one and the same.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1655

6. Claims 1-10, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US 2003/0185884) in view of Frey, II (US 2001/0043915), GB 941664 and Hatsuya et al. (US 5342840) and as evidenced by "Resolution Oeno".

Singh teaches that pilocarpine and its salts are known to be formulated into a dissolving tablet, chewing tablet or the like to be used orally in the buccal cavity, see paragraphs 35, 55, 81, 84, 110, 117, abstract and the claims. Sorbitol and magnesium stearate are also used in the tablet.

Singh does not teach using hyaluronic acid, methylcellulose, lysozyme chlorohydrate, polyethylene glycol or disodium hydrogen phosphate.

Frey teaches that hyaluronic acid is used for buccal administration in tablet form, see paragraphs 86, 89.

Hatsuya teaches that methylcellulose, polyethylene glycol and disodium hydrogen phosphate are all well known common pharmaceutical components and are also used in tablet form, see col. 11, lines 27-end.

GB teaches that lysozyme which is the same as lysozyme chlorohydrate (see "Resolution Oeno") is used in sublingual tablet form, see entire reference.

Art Unit: 1655

It would have been obvious to one having ordinary skill in the art to use all of the claimed components together since they are known to be used in a tablet.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.  
<[http://www.uspto.gov/web/offices/pac/mpep/documents/2100\\_2144.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm)>

Art Unit: 1655

Indeed, the tablet is known to be in a form for sublingual administration, see Frey, GB and Singh. Thus, it was clearly within the purview of the ordinary artisan to use all of the components together to be in a single tablet used for sublingual administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller  
Primary Examiner  
Art Unit 1655

/Michael V. Meller/  
Primary Examiner, Art Unit 1655